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| 09/677,592 | 10/03/2000 | Andrew W. Murray | 215538.00210 | 5305 |

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| EXAMINER |
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FETTEROLF, BRANDON J

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,592

Applicant(s)

MURRAY, ANDREW W.

Examiner

Brandon J. Fetterolf, PhD

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/23/2005</u> . | 6) <input checked="" type="checkbox"/> Other: <u>google search</u> . |

Art Unit: 1642

Murray et al.

DETAILED ACTION

The Amendment filed on 03/23/2005 in response to the previous Non-Final Office Action (10/21/2004) is acknowledged and has been entered.

Claims 1-21 are currently pending.

Claims 8-22 have been withdrawn from consideration as being drawn to non-elected inventions.

Claim 1-7 is currently under consideration.

The Information Disclosure Statement filed on March 23, 2005 is acknowledged and has been considered. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1-7 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record in the prior Office Action (10/21/2004, page 4) and for the reasons set forth below.

In reference to the previous action that held that the use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules, Applicants contend that "one of skill in the art would recognize that "MAD2" refers to a yeast mitotic spindle checkpoint gene." For example, Applicants submit that a simple search of the iHOP database with the term "MAD2" yields a range of accession numbers for the MAD2 gene and protein sequences. Moreover, Applicants argue that the search yields a long list of scientific publications describing the structural and functional attributes of MAD2. Additionally, Applicants submit that the search identifies and hyperlinks to similar information on MAD2 homologs in humans (Exhibit B, Paper No. 1-5). These arguments have been carefully considered and are not found persuasive.

First, while Applicants contend that one of skill in the art would recognize that “MAD2” refers to a yeast mitotic spindle checkpoint gene by providing the results of a “simple” iHOP database search, Applicants have not provided evidence that one of skill in the art would only refer to yeast mitotic spindle checkpoint gene as “MAD2”. For example, a “simple” search of the google database brings up 97,800 instances where the term MAD2 is used. Thus, does this mean that one of skill in the art would recognize that in all of these instances MAD2 refers to yeast mitotic spindle checkpoint? Moreover, a simple search of MAD2 on iHOP not only pulls up MAD2 from yeast, but also referred to ten other genes as “MAD2”. Thus, different laboratories clearly use the same laboratory designations to define completely distinct molecules.

Claims 1-7 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record in the prior Office Action (10/21/2004, pages 4-6) and for the reasons set forth below.

In reference to the previous office action which held that the specification (page 27, lines, 6+, Table 1) appears to only sets forth a mutation in one species of MAD2 (Yeast) in association with a lethal screening strategy for identifying secondary targets, Applicants argue that one skilled in the art would recognize homologs to be structurally similar genes and/or proteins that are part of a family whose members are conserved across a range of species. For example, Applicants submit that the MAD family contains, but is not limited to, Yeast MAD2, Xenopus XMAD, Human hsMAD, and Drosophila MAD. Moreover, Applicants cite (Exhibit C) that a standard definition of “homology” in the context of molecular biology refers to “[s]imilarity in structure of ... a molecule, reflecting a common evolutionary origin. Specifically, such similarity in protein and nucleic acid sequence.” Applicants further submit that Fig. 1A of Li et al. Science 1996, 274, 5285; 246-248 (of record shows an amino acid sequence alignment of human, Xenopus and yeast MAD2 proteins. Additionally, Applicants contend that “mutated MAD2 gene” refers to a variety of known and unknown mutant MAD2 alleles as well as mutants of MAD2 homologs in other species. Thus, Applicants argue that the skilled artisan would have known that a mutated MAD2 gene could be the result of nucleic acid deletions, insertions or substitutions upstream, downstream, within or in between the MAD2 genomic coding regions. These arguments have been carefully considered but are not found persuasive.

Art Unit: 1642

First, the previous rejection was based on whether the specification, at the time the application was filed, described in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of a genus of homologs referred to as “mutated MAD2” in association with a lethal screening strategy for identifying secondary targets. Thus, while Applicants contend that one of skill in the art would recognize homologs to be structurally similar genes and/or proteins further providing a definition and an amino acid sequence alignment of human, *Xenopus* and yeast MAD 2, Applicant’s have not provided evidence that they were in possession of all homologs of a mutated MAD2 gene. Secondly, Applicants contention that one of skill in the art would have known that a mutated MAD2 gene could be the result of nucleic acid deletions, insertions or substitutions upstream, downstream, within or in between the MAD2 genomic coding region is not pertinent because Applicants admit, *supra*, that a mutated MAD2 gene refers to known and unknown mutated MAD2 alleles. Thus, how is one of skill in the art to know that the inventors were in possession of the claimed genus, when applicants admits that mutated MAD2 refers to unknown mutated MAD2 alleles? Lastly, Applicants have not provided evidence that they were in possession of a genus of mutated MAD2 genes in association with a lethal screening strategy for identifying secondary genes. Therefore, only a mutated Yeast MAD2 gene, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph.

New Rejections:***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are indefinite because it recites the phrase “effecting one or more mutations in the genome”. The phrase is not defined by the claims or the specification and therefore, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. In the instant case, it appears as if a mutation already present on a secondary gene is being effected.

Art Unit: 1642

However, it cannot be determined whether the phrase refers to causing a mutation or further altering an existing mutation.

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claim 1 as amended refers to a method of identifying a drug that inhibits the growth or replication of a cell having a mutated MAD2 gene or homolog thereof, said method comprising the steps of: (a) identifying a secondary gene comprising: (1) providing a plurality of cells having a genome, which includes at least one mutated MAD2 gene or homolog thereof; (2) effecting one or more mutations in the genome of said cells, at one or more secondary genes; (3) selecting those cells having at least one mutation that proves lethal to said cells only when said mutated MAD2 gene is present; (4) determining a site in the genome of said cells in which said at least one lethal mutation is located, to provide a secondary gene; (b) contacting a cell having a mutated MAD2 gene or homolog thereof with a drug; and (c) identifying said drug by determining whether the drug modulates the activity of the wildtype secondary gene identified in step (a), such that the drug is lethal to said cell having a mutated MAD2 gene but not to a wildtype cell. Although the specification has support for step (a), e.g. identifying a secondary gene (see specification page 41), the specification as originally filed does not have support for this limitation in the scope of identifying a drug that inhibits growth or replication of a cell having a mutated MAD2 gene. For example, step (a) identifies a mutated secondary gene that is synthetically lethal when combined with MAD2, but step (c) determines the activity of the wildtype secondary gene. Applicant is invited to point to clear support or specific examples of the claimed limitation in the specification as-filed or remove such amendatory language in response to this office action.

Therefore, NO claim is allowed.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

NOTE: If applicants are not able to overcome the NEW MATTER REJECTION under 35 U.S.C. 112, first paragraph, and amend claim 1 to the original, the rejections under 35 U.S.C. 102 and 103 will be reapplied.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

Jeffrey Siew
JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/29/05